(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 485 903 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
16.10.1996 Bulletin 1996/42

(51) Int. Cl.[6]: A61M 25/10

(21) Application number: 91119073.4

(22) Date of filing: 08.11.1991

(54) Catheter balloon, balloon catheter equipped with the balloon, and method of manufacturing the balloon

Ballon für Katheter, mit dem Ballon ausgerüsteter Katheterballon und Verfahren zur Herstellung des Ballons

Ballon pour cathéter, cathéter à ballonnet équipé avec le ballon et procédé de sa fabrication

(84) Designated Contracting States:
BE DE FR GB IT NL SE

(30) Priority: 10.11.1990 JP 304559/90

(43) Date of publication of application:
20.05.1992 Bulletin 1992/21

(73) Proprietor: TERUMO KABUSHIKI KAISHA
Tokyo 151 (JP)

(72) Inventor: Ozasa, Hitoshi,
c/o Terumo Kabushiki Kaisha
Ashigarakami-gun, Kanagawa (JP)

(74) Representative: Casalonga, Axel
BUREAU D.A. CASALONGA - JOSSE
Morassistrasse 8
80469 München (DE)

(56) References cited:
EP-A- 0 274 411
EP-A- 0 318 919
EP-A- 0 362 826
WO-A-89/07958

Printed by Rank Xerox (UK) Business Services
2.13.8/3.4

Description

The present invention relates to a balloon used for various kinds of balloon catheters, especially for a dilatation catheter used for expanding a stenotic lesion in the blood vessel, a catheter equipped with the balloon, and the method of manufacturing the balloon.

There are proposed some methods of manufacturing a balloon for a catheter balloon. For example, is a method of manufacturing a biaxially-drawn polymer balloon proposed, in which a thin wall tubular parison is formed out of a drawable semicrystalline polymer, the parison is stretched out in the direction of its length and then inflated radially at a temperature ranging from the second-order transition temperature to the first-order transition temperature, and the thus-drawn parison is cooled below the second-order transition temperature and deflated.

Another method of manufacturing a biaxially-drawn polymer balloon is proposed in Japanese Patent Provisional Publication gazette No. 183070/1988 (JP-A-63-183070), in which the parison drawn by the same method is heated to a temperature above the drawing temperature while drawn to raise the crystallinity and then cooled below the second-order transition temperature.

The catheter balloon manufactured by the above conventional methods consists of a cylindrical portion of uniform diameter, tapered portions at the front and rear of the cylindrical portion, and thinner cylindrical connecting portions at the front and rear of the tapered portions.

The wall thickness of the catheter balloon made by the above methods is not uniform and the walls of both tapered portions are thicker than that of the cylindrical portion. More specifically, the wall thickneses b1 and b2 of the middle parts of the tapered portions are thicker than the thickness a of the cylindrical portion as shown in Figure 4. Here the middle part of the tapered portions 3a and 3b means the vicinity of the middle point of their length along the axis of the balloon 1. Because of their thicker walls, the tapered portions wrinkle when the balloon is folded and the wrinkles are angular, protuberant and stiff. These wrinkles can hinder the smooth insertion of the balloon into a stenotic lesion in the blood vessel or hurt the inside surface of the blood vessel to cause thrombosis or stenosis.

EP-0 318 919 discloses a method of forming an inflatable medical balloon which comprises:

a) providing a tube of a selected resin of wall thickness and diameter suitable for being formed into a balloon for a balloon catheter device;
b) selectively heating to drawing temperature a defined region of said tube at an end of the portion of the tube from which the balloon is to be formed;
c) applying tension in opposite directions to respective ends of said heated region to draw the region to a smaller diameter, thereby providing a preform having, at the end of said portion of tube, a tapered relatively small diameter region comprised of material that has substantially no crystallization or molecular orientation;
d) thereafter heating said tubular preform to blowing temperature and, while heated, forming a balloon by drawing and blowing said preform including said tapered region; and
e) mounting said balloon to form a balloon catheter device,

said step of preforming said tapered end region enabling the corresponding section of the blown balloon to have a separately controllable thickness profile.

The drawing to form the preform and the step of drawing and blowing the preform are so related that the wall thickness of the main body of the balloon and the wall thickness of a tapered transition section of the balloon are of substantially equal value or the wall of the transition section is thinner.

The present invention provides an improved catheter balloon the protrusion and angulateness of the tapered portions of which when folded are small and soft and which can be inserted into the blood vessel without hurting the inside surface of the blood vessel and easily passed through a stenotic lesion.

The present invention also provides a balloon catheter using the balloon of the present invention and a method of manufacturing a catheter balloon.

The catheter balloon of the present invention is made of a polymer, and comprises a cylindrical portion of substantially uniform diameter, tapered portions at the front and rear of the cylindrical portion and connecting portions at the front and rear of the tapered portions, the wall thicknesses (B) of middle parts of the tapered portions being equal to or smaller than 1.2 times the wall thickness (A) of the cylindrical portion ($B/A \leq 1.2$). According to the present invention, the wall thickness of the front tapered portion is thinner than the wall thickness of the rear tapered portion.

The balloon catheter of the present invention comprises a tubular catheter body and a balloon, the balloon being made of a polymer and comprising a cylindrical portion of substantially uniform diameter, tapered portions at the front and rear of the cylindrical portion and connecting portions at the front and rear of the tapered portions, the wall thicknesses (B) of middle parts of the tapered portions being equal to or smaller than 1.2 times the wall thickness (A) of the cylindrical portion ($B/A \leq 1.2$), and the wall thickness of the front tapered portion being thinner than the wall thickness of the rear tapered portion.

The method of the present invention of manufacturing a catheter balloon comprises forming a tubular parison made of a drawable polymer, heating the tubular parison at a temperature ranging from the second-order transition temperature to the first-order transition temperature of the polymer used, then stretching it in the direction of its axis and then inflating it radially while

heated, thereafter cooling the stretched and inflated tubular parison below the second-order transition temperature of the polymer, and then deflating it to form a crude balloon thus having a cylindrical portion of a substantially uniform desired diameter and desired wall thickness, tapered portions having wall thicknesses thicker than desired at the front and rear of the cylindrical portion and connecting portions at the front and the rear of the tapered portions, and then redrawing the tapered portions of the crude balloon to reduce their wall thicknesses to desired thicknesses by stretching the tapered portions in the direction of the axis of the crude balloon, the redrawing rate of the front tapered portion being higher than the redrawing rate of the rear tapered portion. By this method, the catheter balloon of the present invention can be manufactured easily at a low cost.

Figure 1 is a sectional view of an embodiment of the catheter balloon of the present invention.

Figure 2 is a sectional view of the metal mold for forming the balloon of the present invention.

Figure 3 is a sectional view of a jig for redrawing a crude balloon.

Figure 4 is a sectional view of the partially formed crude balloon before it has been drawn/redrawn.

Figure 5 is a sectional view of the distal end portion of a dilatation catheter comprising of the catheter balloon of the present invention.

Figure 6 is a sectional view of the proximal end portion of the same balloon catheter.

Figure 7 is a diagrammatic view of the balloon of the present invention attached to a catheter body and folded around the catheter body.

Figure 8 is a diagrammatic view of a conventional balloon attached to a catheter body and folded around the catheter body.

Figure 1 is a sectional view of an embodiment of the catheter balloon of the present invention.

A catheter balloon 1 of the present invention is made of a polymer, and comprises a cylindrical portion 2 of substantially uniform diameter, tapered portions 3a and 3b at the front and rear of the cylindrical portion and tubular connecting portions 4a and 4b at the front and rear of the tapered portions, and is characterized in that the wall thicknesses (B) of the middle parts of the tapered portions are equal to or smaller than 1.2 times the wall thickness (A) of the cylindrical portion ($B/A \leq 1.2$). Since the walls of the tapered portions are thin, the protrusion and angulateness of wrinkles caused by the tapered portions when the balloon is folded are smaller and softer than those of conventional balloons. Therefore, the balloon of the present invention, when used in a dilatation catheter, can be inserted easily in the blood vessel without hurting the inside surface of the blood vessel and thereby causing new thrombosis or stenosis.

This balloon 1 is intended to be used with a dilatation catheter. The balloon 1 is made of a polymer. It is folded around the tubular catheter body when the balloon is deflated.

The cylindrical portion 2 has the largest diameter of the balloon and as mentioned above is of uniform diameter over its length. In the meaning of the present invention, the expression "cylindrical portion 2" not only designates a right cylinder, but is also intended to encompass polygonal prismatic configurations.

The tapered portions 3a and 3b extend from the front and rear ends of the cylindrical portion 2 respectively and become gradually smaller in diameter.

The connecting portions 4a and 4b extend respectively from the front and rear tapered portions 3a and 3b and have a cylindrical configuration of a substantially uniform diameter smaller than that of the cylindrical portion 2. The balloon 1 is attached to a catheter body by the connecting portions 4a and 4b.

The tapered portions 3a and 3b and the connecting portions 4a and 4b may be different from each other in their configuration and diameter as shown in Figure 1.

The outside diameter of the cylindrical portion 2 when the balloon is expanded is 1.0 to 35.0 mm, preferably 1.5 to 35.0 mm, the length of the cylindrical portion 2 is 3.0 to 80.0 mm, preferably 10.0 to 75.0 mm, and the overall length of the balloon is 5.0 to 120.0 mm, preferably 15.0 to 100.0 mm.

As shown in Figure 1, the wall thickness A of the cylindrical portion 2 and those indicated by B1 and B2 of the middle parts of the tapered portions 3a and 3b are formed so that be $B1/A \leq 1.2$, preferably $0.3 \leq B1/A \leq 0.9$ or $B1/A \leq 1.2$ and $B2/A \leq 1.2$, preferably $0.3 \leq B1/A \leq 0.9$ and $0.3 \leq B2/A \leq 0.9$.

If B1/A (and B2/A) is equal to or smaller than 0.9, the protrusion and angulateness of the tapered portions 3a and 3b when the balloon is folded are small and soft. If B1/A (and B2/A) is equal to or greater than 0.3, the walls of the tapered portions 3a and 3b have an adequate strength. According to the invention the wall thickness B1 of the front tapered portion 3a is thinner than the wall thickness B2 of the rear tapered portion 3b ($B1<B2$).

It is preferable that the balloon 1 be drawn biaxially. For this purpose, the balloon 1 is drawn both in the direction of its axis and in the direction perpendicular to its axis. By thus drawing biaxially, the wall thickness of the balloon 1 becomes thinner and the strength of the balloon 1 increases.

It is further preferable that the tapered portions 3a and 3b are redrawn. By redrawing the tapered portions 3a and 3b, their wall thicknesses can be made thinner as desired.

Polymers usable for the balloon of the present invention are, for example, poly(ethylene terephthalate), a polyester (ethylene terephthalate copolymer) having a different principal acid or principal glycol, a mixture of poly(ethylene terephthalate) and a polyester other than poly(ethylene terephthalate), a mixture of poly(ethylene terephthalate) and polyolefin (for example, polyethylene and polypropylene), or poly(ethylene terephthalate) copolymer.

The polyesters usable for the balloon of the present invention are those obtained using isophthalic acid, orthophthalic acid, naphthalene dicarboxylic acid, paraphenylene dicarboxylic acid, cyclohexane dicarboxylic acid, succinic acid, glutaric acid, adipic acid, suberic acid, azelaic acid, sebacic acid, dodecane-dicarboxylic acid, trimellitic acid, pyromellitic acid, sulfoisophthalic acid and their salts for the principal acid and using polypropylene glycol, butanediol, pentanediol, hexanediol, neopentyle glycol, diethylene glycol, triethylene glycol, polyethylene glycol, polytetramethylene glycol, cyclohexane dimethanol, bisphenol-A-ethylene oxide adduct, trimethylol propane, pentaerythritol for the principal glycol.

In the method of the present invention for manufacturing a catheter balloon, a tubular parison is first formed of a drawable or orientable polymer. Next the parison is heated at a temperature in the range from the second-order transition temperature to the first-order transition temperature of the polymer used. The heated parison is stretched in the direction of its axis and then inflated radially. While stretched and inflated, the parison is cooled below the second-order transition temperature of the polymer and deflated. Thus obtained is a partially shaped or crude balloon. Next the tapered portions of the crude balloon are redrawn by stretching to reduce their wall thickness. The balloon is inflated again and heated above the second transition temperature of the polymer. The balloon is cooled while inflated and deflated.

Each step of the above process is described below in detail.

First, a tubular parison 17 as shown in Figure 2 is formed of a drawable polymer. The polymers described above can be used for the material.

Next, the tube 17 is put into a metal mold 10 as shown in Figure 2 and one end of the tubular parison 17 is clamped in an air-tight fashion (not shown). The clamping is made by melting under heat or by means of a forceps. Figure 2 is a sectional view of a metal mold 10 for forming the balloon. The metal mold 10 is provided with a heating coil 12 and a cooling conduit 13. The metal mold 10 is of the divided type and comprises metal mold parts 15 and 16 the inside surfaces of which are formed to conform to the external shape of the crude balloon when the metal mold parts 15 and 16 are combined.

As shown in Figure 2, the tubular parison 17 is then heated to a temperature in the range from the second-order transition temperature to the first-order transition temperature of the polymer used, more specifically a temperature slightly higher than the second-order transition temperature, by turning on heater 12. While being heated, the tubular parison 17 is stretched along its axis by pulling it in the directions indicated by arrows X and Y, then inflated by introducing air under pressure in the direction indicated by Z so that the heated part of the tubular parison 17 is tightly pressed against the inside surfaces of the metal mold parts 15 and 16. While inflated, the tubular parison 17 is cooled below the second-order transition temperature of the polymer by circulating a cooling liquid in the cooling conduit 13. The tubular parison 17 may also be cooled by free cooling, that is without using a cooling liquid. After the tubular parison 17 has cooled, the air inside the tubular parison 17 is released and the tubular parison 17 is taken out from the metal mold 10. Then the front and rear end portions of the tubular parison 17 are cut off and a biaxially-drawn or biaxially-oriented crude balloon 50 as shown in Figure 4 is obtained. The crude balloon has a cylindrical portion of a substantially uniform desired diameter and desired wall thickness, tapered portions of wall thickness thicker than a desired thickness at the front and rear of the cylindrical portion and connecting portions at the front and the rear of the tapered portions. This drawing process may be repeated two or more times as necessary to obtain a crude balloon with the desired wall thickness.

The tapered portions 3a and 3b of the crude balloon are redrawn to reduce their wall thicknesses. Figure 3 is a sectional view of a jig for stretching the tapered portions 3a and 3b. The jig 20 has two clamps 25a and 25b for holding firmly the crude balloon. The clamp 25b is movably supported on a base 28 and can be moved toward and away from the other clamp 25a by turning a crank 22 on the end of a threaded bar. Any desired part of the crude balloon can be stretched by clamping both sides of that part with the clamps 25a and 25b and then moving clamp 25b to increase distance L between clamps 25a and 25b by turning the crank 22. The wall thickness of the tapered portions 3a and 3b can be made thinner as desired by this redrawing. It is preferable the redrawing rate of the front tapered portion 3a be higher than the redrawing rate of the rear tapered portion 3b. It is preferable to heat the parts of the crude balloon before stretching. The connecting portions 4a and 4b may be stretched together with the tapered portions 3a and 3b as necessary.

After being stretched, the balloon is placed into a metal mold (not shown), inflated by pressured air, heated above the second-order transition temperature of the polymer and then cooled below that temperature while inflated. As the result, the balloon 1 of the present invention is obtained.

A balloon catheter according to the present invention will now be described in connection with Figures 5 and 6.

Figure 5 is a sectional view of the distal end portion of a catheter, and Figure 6 is a sectional view of the proximal end portion of the same catheter.

In the embodiment shown in Figures 5 and 6 the catheter is a dilatation catheter equipped with the catheter balloon of the present invention.

The balloon catheter 30 consists of a tubular catheter body comprising an inner tube 24, an outer tube 35, a branched sleeve 31 and a balloon 1.

The inner tube 24 has a first lumen 34 terminated by open proximal and distal ends. The first lumen 34 is

used for passing a guide wire and is in communication with a first bore 39 in sleeve 31 (described later) serving as a guide wire port. Inner tube 24 has an outside diameter of 0.30 to 2.50 mm, preferably 0.40 to 2.00 mm and an inside diameter of 0.20 to 2.35 mm, preferably 0.25 to 1.70 mm.

Preferably the material forming the inner tube 24 will have a certain amount of flexibility. Materials usable for the inner tube 24 are thermoplastic resins [such as polyolefin (polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetate copolymer, etc.), polyvinyl chloride, polyurethane, polyamide elastomer], silicone rubber and latex rubber. Of the above materials, thermoplastic resins are preferable and olefin resins are more preferable.

Outer tube 35 surrounds inner tube 24 and is shorter than the inner tube 24 so as to allow the distal end portion of the inner tube 24 to extend out of its distal end. Outer tube 35 is sized so that a second lumen 36 is formed between the inside surface of the outer tube 35 and the outside surface of the inner tube 24. The second lumen 36 is in communication with the inside of the balloon 1 at its distal end. The proximal end of the second lumen 36 is in communication with a second bore 41 in branched sleeve 31 used as an injection port to inject a liquid for expanding the balloon 1.

The outer tube 35 has an outside diameter of 0.50 to 4.30 mm, preferably 0.60 to 4.00 mm and an internal diameter of 0.40 to 3.80 mm, preferably 0.50 to 3.00 mm.

Preferably the material for forming the outer tube 35 will have a certain amount of flexibility. The materials usable for the outer tube 35 are thermoplastic resins [such as polyolefin (polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetate copolymer, etc.), polyvinyl chloride, polyurethane, polyamide elastomer], silicone rubber and latex rubber. Of the above materials, thermoplastic resins are preferable and olefin resins are more preferable.

The balloon 1 is foldable and is folded around the inner tube 24 when it is not expanded. It has a hollow cylindrical portion 2 of a substantially uniform diameter so that a stenotic lesion in the blood vessel can be easily dilated. The cylindrical portion 2 may not necessarily be in the shape of a right cylinder but may as well be in the shape of a prism. A connecting portion 4b of the balloon 1 is connected with the distal end portion of the outer tube 35 in a liquid-tight manner by means of adhesive bonds or by heating. The other connecting portion 4a is connected with the inner tube 24 near the distal end in the same manner as the connecting portion 4b.

The outside surface of the inner tube 24 from the front end of the connecting portion 4a to the distal end of the inner tube 24 is coated with a soft resin layer 5. The rear end of the soft resin layer 5 has substantially the same thickness as that of the connecting portion 4a to fill the step at the front end of the connecting portion 4a. The front end of the soft resin layer 5 is so rounded by cutting off the outside edge that the rounded end of the soft resin layer 5 and that of the inner tube 24 form a continuous curved surface. The soft resin layer 5 and its rounded front end reduce the frictional resistance between the distal end of the balloon catheter (the distal end of the inner tube) and the inside surface of a guide catheter when the balloon catheter is inserted through the guide catheter and between the distal end of the balloon catheter and the inside surface of the blood vessel when the balloon catheter is advanced in the blood vessel.

Balloon 1 forms a hollow space 45 between its inside surface and the outside surface of the inner tube 24. The rear end of the hollow space 45 is in communication with the second lumen 36. Since the second lumen 36 has a comparatively large sectional area, injection of a liquid into the balloon 1 is easy.

Balloon 1 has tapered portions 3a and 3b formed from the front end of the cylindrical portion 2 to the front connecting portion 4a and from the rear end of the cylindrical portion 2 to the rear connecting portion 4b.

The outside diameter of the cylindrical portion when expanded is 1.00 to 35.00 mm, preferably 1.50 to 3.00 mm; the length of the cylindrical portion when expanded is 3.00 to 80.00 mm, preferably 10.00 to 75.00 mm; and the overall length of the balloon is 5.00 to 120.00 mm, preferably 15.00 to 100.00 mm.

As shown in Figure 1, the wall thickness A of the cylindrical portion 2 and those indicated by B1 and B2 of the middle parts of the tapered portions 3a and 3b are formed so that $B1/A \leq 1.2$, preferably $0.3 \leq B1/A \leq 0.9$ or $B1/A \leq 1.2$ and $B2/A \leq 1.2$, preferably $0.3 \leq B1/A \leq 0.9$ and $0.3 \leq B2/A \leq 0.9$. According to the invention the wall thickness B1 of the front tapered potion 3a is thinner than the wall thickness B2 of the rear tapered portion 3b.

It is also preferable to provide the outside surface of the inner tube 24 with a marker 44 to facilitate the X-ray localization of the cylindrical portion 2. Preferably the marker 44 has substantially the same length as that of the cylindrical portion 2 and is disposed on the outside surface of the inner tube 24 inside the hollow space of the balloon 1 so that its ends are substantially at the same positions as those of the cylindrical portion 2. For the material of the marker 44, substances impervious or only slightly pervious to radiation such as gold, platinum, tungsten, stainless-steel and their alloys and silver-palladium alloys are preferable. A preferable configuration of marker 44 is a coil spring, and more preferably a coil spring having closely coiled portions of 1 to 4 mm, preferably 2 to 3 mm at both ends as shown in Figure 5. A marker of coil spring configuration provides also a reinforcement which prevents bending and collapsing of the inner tube 24 in the blood vessel. The closely coiled portions at the ends of a spring coil make the X-ray localization of the cylindrical portion 2 easier.

Moreover, if a single closely-coiled coil spring is fitted on the outside surface of the inner tube 24, the flexural rigidity of this portion is much more increased.

The cross section of the wire material of the coil spring may be rectangular, circular, square, elliptic or of any other shape.

The branched sleeve 31 consists of a inner-tubular element 52 and an outer-tubular element 53.

Inner tubular element 52 is attached to the proximal end of the inner tube 24 and provided with the aforementioned first bore 39 communicating with the first lumen 34 and serving as a guide wire port.

The outer tubular element 53 is attached to the proximal end of the outer tube 35 and provided with the aforementioned second bore 41 communicating with the second lumen 36 and serving as a injection port.

The inner tubular element 52 and outer tubular element 53 are connected together into one body.

In the embodiment shown in Figure 6, a reinforcing tube 50 is fitted over the proximal end portion of the outer tube 35. The reinforcing tube 50 is made of a heat-shrinkable material. Reinforcing tube 50 is fitted on the outer tube 35 by forming tube 50 so that its inside diameter is slightly greater than the outer diameter of the outer tube, placing it on the outer tube, and heating it, for example, by blowing hot air.

The proximal end of the outer tube 35 is secured to the outer tubular element 53 by means of a clamping member 61. Clamping member 61 has a cylindrical portion of about the same outside diameter as the inside diameter of the outer tube 35 and about the same inside diameter as the outside diameter of the inner tube 24 and a flared rear end portion of a diameter greater than the outside diameter of the reinforcing tube 50. To secure the outer tube 35 to the outer tubular element 53, the clamping member 61 is inserted into the rear end of the outer tube 35 and the outer tube 35 is then inserted into the outer tubular element 53 from the distal end until the flared rear end of the clamping member 61 overrides a projection 54 in the inside surface of the outer tubular element 53. An adhesive bond may be applied between the inside surface of the outer tubular element 53 and the outside surface of the reinforcing tube 50.

Preferable materials for the outer tubular element 53 are thermoplastic resins such as polycarbonate, polyamide, polysulfone, polyacrylate and methacrylate-butylene-styrene-copolymer.

A reinforcing tube 60 is fitted over the proximal end portion of the inner tube 24. The reinforcing tube 60 is made of a heat-shrinkable material. Reinforcing tube 60 is fitted on the inner tube 24 by forming tube 60 so that its inside diameter is slightly greater than the outside diameter of the inner tube, putting it on the inner tube, and heating it, for example, by blowing hot air.

The proximal end of the inner tube 24 is secured to the inner tubular element 52 by means of a clamping member 62. Clamping member 62 has a cylindrical portion of about the same outside diameter as the inside diameter of the inner tube 24 and a flared rear end portion of a diameter greater than the outside diameter of the reinforcing tube 60. To secure the inner tube 24 to the inner tubular element 52, the clamping member 62 is inserted into the rear end of the inner tube 24 and the inner tube 24 is then inserted into the inner tubular element 52 from the distal end until the flared rear end of the clamping member 62 overrides a projection 64 in the inside surface of the inner tubular element 52. An adhesive bond may be applied between the inside surface of the inner tubular element 52 and the outside surface of the reinforcing tube 60.

Preferable materials for the inner-tube 52, thermoplastic resins such as polycarbonate, polyamide, polysulfone, polyacrylate and methacrylate-butylene-styrene-copolymer.

The inner tubular element 52 and the outer tubular element 53 are connected together by fitting the front end portion of the inner tubular element 52 in the rear end portion of the outer tubular element 53 as shown in Figure 6. They can be securely connected by applying an adhesive bond.

Instead of such a sleeve, tubular port members with a bore in their rear end may be connected to the inner and outer tubes respectively in a liquid-tight fashion so that the bore of each port member is in communication with the corresponding lumen of the balloon.

Example 1

A tubular parison was formed of high molecular weight poly(ethylene terephthalate) of the specific viscosity of about 1.1 (UNIPET® RT580 from Japan Unipet, molecular weight about 40,000) by extrusion molding. This parison was 0.6 mm inside diameter, 1.0 mm outside diameter, and 0.2 mm wall thickness.

The parison was placed in a metal mold as shown in Figure 2, heated at 85 °C, stretched 1.6 times in the direction of its axis, inflated by pressured air so as to be pressed tightly against the inside surface of the metal mold, and cooled. The drawing ratio of the cylindrical portion resulting from the inflation was about 5 on the inside diameter and about 3 on the outside diameter.

The wall thicknesses of the crude balloon a, b1, and b2 shown in Figure 4 were 0.013 mm, 0.020 mm and 0.016 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions f/d and f/e were 2.31 and 2.00. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion b1/a and b2/a were 1.54 and 1.23 respectively.

Each tapered portion of this crude balloon was stretched about 3 times in the direction of the axis of the crude balloon using a jig as shown in Figure 3. The crude balloon was then inflated by pressured air and heated at 150 °C to heat set. Thus the balloon of the present invention was obtained.

The wall thicknesses of the balloon A, B1, B2, D, E and F shown in Figure 1 were 0.013 mm, 0.013 mm, 0.010 mm, 0.80 mm, 1.20 mm and 3.00 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions F/D and

F/E were 3.75 and 2.50 respectively. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion B1/A and B2/A were 1.00 and 0.77 respectively.

Example 2

A tubular parison was formed of PET copolymer resin (copolymer of polyethylene and terephthalic acid and isophthalic acid) of the specific viscosity of about 0.8 (UNIPET® RN165 from Japan Unipet, molecular weight about 30,000) by extrusion molding. This parison has an inside diameter of 0.40 mm, an outside diameter of 0.72 mm, and a wall thickness of 0.16 mm.

A crude balloon was formed from this parison by heating it at 85 °C, stretching it in the direction of its axis and inflated it in the same manner as in example 1. The drawing ratio in the direction of the axis was 2.5. The drawing ratio of the cylindrical portion resulting from the inflation was about 4.9 on the inside diameter and about 2.8 on the outside diameter.

The wall thicknesses of the crude balloon a, b1, and b2 shown in Figure 4 were 0.011 mm, 0.016 mm and 0.014 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions f/d and f/e were 2.00 and 1.67 respectively. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion b1/a and b2/a were 1.45 and 1.27 respectively.

Each tapered portion of this crude balloon was stretched about 3 times (but, the drawing rate of the front tapered portion was higher than the drawing rate of the rear tapered portion) in the direction of the axis of the crude balloon while heating the tapered portion and connecting portion at about 100 °C by hot air. This crude balloon was inflated again and heated at 150 °C.

The wall thicknesses of the balloon A, B1, and B2 shown in Figure 1 were 0.011 mm, 0.009 mm and 0.010 mm. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions F/D and F/E were 2.50 and 1.67 respectively. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion B1/A and B2/A were 0.82 and 0.91 respectively.

Example 3

A tubular parison was formed of PET copolymer resin of the specific viscosity of about 0.8 (UNIPET® RN165 from Japan Unipet, molecular weight about 30,000) by extrusion molding. This parison had an inside diameter of 0.6 mm, an outside diameter of 1.082 mm and a wall thickness of 0.24 mm.

A crude balloon was formed from this parison by heating it at 90 °C, stretching it in the direction of its axis and inflated it in the same manner as in example 1. The drawing ratio in the direction of the axis was 2.5. The drawing ratio of the cylindrical portion resulting from the inflation was about 5.8 on the inside diameter and about 3.2 on the outside diameter.

The wall thicknesses of the crude balloon a, b1, and b2 shown in Figure 4 were 0.016 mm, 0.028 mm and 0.023 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions f/d and f/e were both 2.92 respectively. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion b1/a and b2/a were 1.75 and 1.44 respectively.

Each tapered portion of this crude balloon was stretched about 3 times (but, the drawing rate of the front tapered portion was higher than the drawing rate of the rear tapered portion) in the direction of the axis of the balloon while heating the tapered portion and connecting portion at about 100 °C by hot air. This crude balloon was then inflated again and heated at 90 °C.

The wall thicknesses of the balloon A, B1, and B2 shown in Figure 1 were 0.015 mm, 0.017 mm and 0.018 mm. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions F/D and F/E were both 2.92 respectively. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion B1/A and B2/A were 1.13 and 1.20 respectively.

Each tapered portion of this balloon was again stretched about 1.2 times in the direction of the axis of the balloon while heating the tapered portion and connecting portion at about 100 °C by hot air. The balloon was then inflated and heated at 150 °C again. Thus the balloon of the present invention was obtained.

The wall thicknesses A, B1, and B2 of the balloon shown in Figure 1 were 0.015 mm, 0.010 mm and 0.013 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions F/D and F/E were 4.83 and 2.92 respectively. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion B1/A and B2/A were 0.67 and 0.87 respectively.

Example 4

A double-layer tube with an inside diameter of 0.95 mm, an outside diameter of 1.17 mm and a length of 1,300 mm was formed of polyethylene and EVA copolymer and used as the outer tube. An inner layer of the tube was formed of polyethylene. An outer layer of the tube was formed of EVA copolymer. A tube with an inside diameter of 0.5 to 0.55 mm, an outside diameter of 0.70 mm and a length of 1,350 mm was formed of polyethylene and used as the inner tube.

A catheter of the construction as shown in Figures 5 and 6 was made using these tubes to form a tubular catheter body and the balloon of example 1.

Example 5

A balloon catheter was made using the catheter body obtained in example 4 and the balloon of example 2.

Example 6

A balloon catheter was made using the catheter body obtained in example 4 and the balloon of example 3.

Comparative Example 1

The crude balloon before restretching in example 1 was used as comparative example 1. The wall thicknesses of the crude balloon a, b1, and b2 shown in Figure 4 were 0.013 mm, 0.020 mm and 0.016 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions f/d and f/e were 2.31 and 2.00 respectively, and those of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion b1/a and b2/a were 1.54 and 1.23 respectively.

Comparative Example 2

A balloon catheter was made using the catheter body obtained in example 4 and the crude balloon of comparative example 1.

Comparative Example 3

The crude balloon before restretching in example 2 was used as comparative example 3. The wall thicknesses of the crude balloon a, b1, and b2 shown in Figure 4 were 0.011 mm, 0.016 mm and 0.014 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions f/d and f/e were 2.00 and 1.67. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion b1/a and b2/a were 1.45 and 1.27 respectively.

Comparative Example 4

The crude balloon before restretching in example 3 was used as comparative example 4. The wall thicknesses of the crude balloon a, b1, and b2 shown in Figure 4 were 0.016 mm, 0.028 mm and 0.023 mm, respectively. The ratios of the outside diameter of the cylindrical portion to those of the connecting portions f/d and f/e were both 2.92. The ratios of the wall thicknesses of the middle parts of the tapered portions to that of the cylindrical portion b1/a and b2/a were 1.75 and 1.44 respectively.

Comparative Example 5

A balloon catheter was made using the catheter body obtained in example 4 and the crude balloon of comparative example 3.

Comparative Example 6

A balloon catheter was made using the catheter body obtained in example 4 and the crude balloon of comparative example 4.

Tests

A syringe was attached to the injection port of the balloon catheter of example 4. The balloon was inflated by injecting a liquid into the second lumen and then folded by sucking the liquid.

The same tests were conducted on the balloon catheters of examples 5 and 6 and comparative examples 2, 5 and 6.

The protrusion and angulateness of the wrinkles caused by the tapered portions were smaller and softer in the balloons of the catheters of examples 4, 5 and 6 than in that of the catheters of comparative examples 2, 5 and 6 as shown in Figures 7 and 8.

Claims

1. A catheter balloon (1) made of a polymer and comprising a cylindrical portion (2) of uniform diameter, tapered portions (3a, 3b) at the front and rear of the cylindrical portion and connecting portions (4a, 4b) at the front and rear of the tapered portions, the wall thicknesses (B) of middle parts of the tapered portions being equal to or smaller than 1.2 times the wall thickness (A) of the cylindrical portion ($B/A \leq 1.2$), characterized in that the wall thickness of the front tapered portion (3a) is thinner than the wall thickness of the rear tapered portion (3b).

2. The catheter balloon of claim 1, characterized in that the wall thicknesses (B) of the middle parts of said tapered portions (3a, 3b) are equal to or greater than 0.3 times and equal to or smaller than 0.9 times the wall thickness (A) of said cylindrical portion ($0.3 \leq B/A \leq 0.9$).

3. The catheter balloon of claim 1 or 2, in which said cylindrical portion (2) and said tapered portions (3a, 3b) are biaxially drawn.

4. A catheter balloon according to anyone of claims 1 to 3, characterized in that said tapered portions are redrawn.

5. The catheter balloon according to anyone of claims 1 to 4, in which said polymer is poly(ethylene terephthalate), a mixture of poly(ethylene tereph-

thalate) and a polyester other than poly(ethylene terephthalate) or polyolefin, or a poly(ethylene terephthalate) copolymer.

6. A balloon catheter (30) comprising a tubular catheter body (24, 31, 35) and a balloon (1), characterized in that said balloon (1) is as set forth in anyone of claims 1 to 5.

7. A method of manufacturing a catheter balloon (1) comprising successively:

   forming a tubular parison (17) out of a drawable polymer;
   heating the parison (17) at a temperature ranging from the second-order transition temperature to the first-order transition temperature of the polymer used;
   stretching it in the direction of its axis and then inflating it radially while heated;
   cooling the stretched and inflated parison below the second-order transition temperature of the polymer;
   deflating it, a crude balloon thus Formed having a cylindrical portion (2) of uniform desired diameter and desired wall thickness, tapered portions (3a, 3b) of wall thicknesses thicker than desired thicknesses at the front and rear of the cylindrical portion and connecting portions (4a, 4b) at the front and the rear of the tapered portions; and
   redrawing the tapered port ions (3a, 3b) of the crude balloon to reduce their wall thicknesses to desired thicknesses by stretching the tapered portions in the direction of the axis of the crude balloon, the redrawing rate of the front tapered portion (3a) being higher than the redrawing rate of the rear tapered portion (3b).

8. The method of manufacturing a catheter balloon as in claim 7, characterized in that it successively comprises inflating the crude balloon after said redrawing, heating is above the second-order transition temperature of the polymer, and cooling it.

9. The method of manufacturing a catheter balloon as in claim 7 or 8 characterized in that said redrawing is carried out so that the thicknesses (B) of the middle parts of the tapered portions (3a, 3b) become equal to or smaller than 1.2 times the wall thickness (A) of the cylindrical portion (B/A ≤ 1.2).

10. The method of manufacturing a catheter balloon as in anyone of claims 7 to 9, characterized in that said redrawing is carried out over the tapered portions (3a, 3b) and connecting portions (4a, 4b) of the crude balloon.

11. The method of manufacturing a catheter balloon as in anyone of claims 7 to 10, in which said step of inflating the tubular parison (17) radially is carried out in a metal mold.

12. The method of manufacturing a catheter balloon as in anyone of claims 7 to 11, characterized in that said step of inflating the redrawn crude balloon is carried out in a metal mold.

13. The method of manufacturing a catheter balloon as in anyone of claims 7 to 12 in which said drawable polymer is poly(ethylene terephthalate), a mixture of poly(ethylene terephthalate) and a polyester other than poly(ethylene terephthalate) or polyolefin, or a poly(ethylene terephthalate) copolymer.

14. The method of manufacturing a catheter balloon as in claim 7 or 13, characterized in that said redrawing is carried out so that the thicknesses (B) of the middle parts of said tapered portions (3a, 3b) are equal to or greater than 0.3 times and equal to or smaller than 0.9 times the wall thickness (A) of said cylindrical portion (0.3 ≤ B/A ≤ 0.9).

Patentansprüche

1. Katheterballon (1), hergestellt aus einen Polymer und umfassend einen zylinderförmigen Abschnitt (2) mit gleichmäßigem Durchmesser, sich verjüngende Abschnitte (3a, 3b) an der Vorder- und Hinterseite des zylindrischen Abschnitts und Verbindungsabschnitte (4a, 4b) an der Vorder- und Hinterseite der sich verjüngenden Abschnitte, wobei die Wandstärken (B) der Mittelteile der sich verjüngenden Abschnitte gleich oder kleiner als 1,2 Mal die Wandstärke (A) des zylindrischen Abschnitts sind (B/A ≤ 1,2), dadurch **gekennzeichnet**, daß die Wandstärke des vorderen sich verjüngenden Abschnitts (3a) dünner als die Wandstärke des hinteren sich verjüngenden Abschnitts (3b) ist.

2. Katheterballon nach Anspruch 1, dadurch **gekennzeichnet**, daß die Wandstärken (B) der Mittelteile der sich verjüngenden Abschnitte (3a, 3b) gleich oder größer als 0,3 Mal und gleich oder kleiner als 0,9 Mal die Wandstärke (A) des zylinderförmigen Abschnitts sind (0,3 ≤ B/A ≤ 0,9).

3. Katheterballon nach Anspruch 1 oder 2, bei dem der zylinderförmige Abschnitt (2) und die sich verjüngenden Abschnitte (3a, 3b) biaxial gezogen sind.

4. Katheterballon nach einem der Ansprüche 1 bis 3, dadurch **gekennzeichnet**, daß die sich verjüngenden Abschnitte nachgezogen sind.

5. Katheterballon nach einem der Ansprüche 1 bis 4, bei dem das Polymer Poly(ethylenterephthalat), eine Mischung aus Poly(ethylenterephthalat) und einem Polyester verschieden von Poly(ethylenterephthalat) oder Polyolefin oder ein Poly(ethylenterephtalat)-Copolymer ist.

6. Ballonkatheter (30) umfassend einen schlauchförmigen Katheterkörper (24, 31, 35) und einen Ballon (1), dadurch **gekennzeichnet**, daß der Ballon (1), nach einem der Ansprüche 1 bis 5 ausgeführt ist.

7. Verfahren zur Herstellung eines Katheterballons (1), nacheinander umfassend, daß:

   ein schlauchförmiger Vorformling (17) aus einem ziehbaren Polymer geformt wird;
   der Vorformling (17) bei einer Temperatur, die von der Umwandlungstemperatur zweiter Ordnung zur Umwandlungstemperatur erster Ordnung des verwendeten Polymers reicht, erwärmt wird;
   er in Richtung seiner Achse gereckt wird und er dann radial während des Erwärmens aufgeblasen wird;
   der gereckte und aufgeblasene Vorformling unter die Umwandlungstemperatur zweiter Ordnung des Polymers gekühlt wird;
   er abgelassen wird, wobei ein derart geformter Rohballon einen zylinderförmigen Abschnitt (2) mit gleichmäßigem gewünschtem Durchmesser und gewünschter Wandstärke, sich verjüngende Abschnitte (3a, 3b) aus Wandstärken dicker als gewünschte Stärken an der Vorder- und Hinterseite des zylinderförmigen Abschnitts und Verbindungsabschnitte (4a, 4b) an der Vorderseite und der Hinterseite der sich verjüngenden Abschnitte aufweist; und
   die sich verjüngenden Abschnitte (3a, 3b) des Rohballons nachgezogen werden, um ihre Wandstärken auf gewünschte Stärken durch Recken der sich verjüngenden Abschnitte in Richtung der Achse des Rohballons zu vermindern, wobei das Ausmaß des Nachziehens des vorderen sich verjüngenden Abschnitts (3a) größer als das Ausmaß des Nachziehens des hinteren sich verjüngenden Abschnitts (3b) ist.

8. Verfahren zur Herstellung eines Katheterballons nach Anspruch 7, dadurch **gekennzeichnet**, daß es nacheinander umfaßt, daß der Rohballon nach dem Nachziehen aufgeblasen wird, er über die Umwandlungstemperatur zweiter Ordnung des Polymers erwärmt wird und er gekühlt wird.

9. Verfahren zur Herstellung eines Katheterballons nach Anspruch 7 oder 8, dadurch **gekennzeichnet**, daß das Nachziehen derart ausgeführt wird, daß die Stärken (B) der Mittelteile der sich verjüngenden Abschnitte (3a, 3b) gleich oder kleiner als 1,2 mal die Wandstärke (A) des zylinderförmigen Abschnitts werden (B/A ≤ 1,2).

10. Verfahren zur Herstellung eines Katheterballons nach einem der Ansprüche 7 bis 9, dadurch **gekennzeichnet**, daß das Nachziehen über die sich verjüngenden Abschnitte (3a, 3b) und Verbindungsabschnitte (4a, 4b) des Rohballons ausgeführt wird.

11. Verfahren zur Herstellung eines Katheterballons nach einem der Ansprüche 7 bis 10, bei dem der Schritt des Aufblasens des schlauchförmigen Vorformlings (17) radial in einer Metallform ausgeführt wird.

12. Verfahren zur Herstellung eines Katheterballons nach einem der Ansprüche 7 bis 11, dadurch **gekennzeichnet**, daß der Schritt des Aufblasens des nachgezogenen Rohballons in einer Metallform ausgeführt wird.

13. Verfahren zur Herstellung eines Katheterballons nach einem der Ansprüche 7 bis 12 bei dem das ziehbare Polymer Poly(ethylenterephthalat), eine Mischung aus Poly(ethylenterephthalat) und einem Polyester verschieden von Poly(ethylenterephthalat) oder Polyolefin, oder ein Poly(ethylenterephthalat)-Copolymer ist.

14. Verfahren zur Herstellung eines Katheterballons nach Anspruch 7 oder 13, dadurch **gekennzeichnet**, daß das Nachziehen derart ausgeführt wird, daß die Stärken (B) der Mittelteile der sich verjüngenden Abschnitte (3a, 3b) gleich oder größer als 0,3 Mal und gleich oder kleiner als 0,9 Mal die Wandstärke (A) des zylinderförmigen Abschnitts sind (0,3 ≤ B/A ≤ 0,9).

Revendications

1. Ballonnet de cathéter (1) fait d'un polymère et comprenant une partie cylindrique (2) de diamètre uniforme, des parties coniques (3a, 3b) à l'avant et à l'arrière de la partie cylindrique et des parties de raccordement (4a, 4b) à l'avant et à l'arrière des parties coniques, l'épaisseur de paroi (B) des parties du milieu des parties coniques étant inférieure ou égale à 1,2 fois l'épaisseur de paroi (A) de la partie cylindrique (B/A ≤ 1,2), caractérisé en ce que l'épaisseur de paroi de la partie conique avant (3a) est plus petite que l'épaisseur de paroi de la partie conique arrière (3b).

2. Ballonnet de cathéter selon la revendication 1, caractérisé en ce que l'épaisseur de paroi (B) des parties du milieu desdites parties coniques (3a, 3b) est supérieure ou égale à 0,3 fois l'épaisseur de

paroi (A) de ladite partie cylindrique et est inférieure ou égale à 0,9 fois l'épaisseur de paroi (A) de ladite partie cylindrique ($0,3 \leq B/A \leq 0,9$).

3. Ballonnet de cathéter selon la revendication 1 ou 2, dans lequel ladite partie cylindrique (2) et lesdites parties coniques (3a, 3b) sont étirées biaxialement.

4. Ballonnet de cathéter selon l'une quelconque des revendications 1 à 3, caractérisé en ce que lesdites parties coniques sont réétirées.

5. Ballonnet de cathéter selon l'une quelconque des revendications 1 à 4, dans lequel ledit polymère est du poly(téréphtalate d'éthylène), un mélange de poly(téréphtalate d'éthylène) et d'un polyester autre que le poly(téréphtalate d'éthylène) ou une polyoléfine, ou bien un copolymère de poly(téréphtalate d'éthylène).

6. Cathéter à ballonnet (30) comprenant un corps de cathéter tubulaire (24, 31, 35) et un ballonnet (1), caractérisé en ce que ledit ballonnet (1) est tel que revendiqué dans l'une quelconque des revendications 1 à 5.

7. Procédé de fabrication d'un ballonnet de cathéter (1) comprenant successivement :

- la formation d'une paraison tubulaire (17) à partir d'un polymère étirable,
- le chauffage de la paraison (17) à une température allant de la température de transition du second ordre à la température de transition du premier ordre du polymère utilisé,
- l'étirage de cette paraison dans la direction de son axe et son gonflage radial pendant qu'elle est chauffée,
- le refroidissement de la paraison tubulaire étirée et gonflée en-dessous de la température de transifion du second ordre du polymère,
- son dégonflage pour former un ballonnet cru comprenant ainsi une partie cylindrique (2) d'un diamètre uniforme voulu et d'une épaisseur de paroi désirée, des parties coniques (3a, 3b) ayant une épaisseur de paroi plus forte que l'épaisseur souhaitée à l'avant et à l'arrière de la partie cylindrique et des parties de raccordement (4a, 4b) à l'avant et à l'arrière des parties coniques, et
- un ré-étirage des parties coniques (3a, 3b) du ballonnet cru afin de réduire leur épaisseur de paroi à la valeur souhaitée par étirage des parties coniques dans la direction de l'axe du ballonnet cru, le degré de ré-étirage de la partie conique avant (3a) étant plus élevé que le degré de ré-étirage de la partie conique arrière (3b).

8. Procédé de fabrication d'un ballonnet de cathéter selon la revendication 7, caractérisé en ce qu'il comprend successivement le gonflage du ballonnet cru après ledit ré-étirage, son chauffage au-dessus de la température de transition du second ordre du polymère et son refroidissement.

9. Procédé de fabrication d'un ballonnet de cathéter selon la revendication 7 ou 8, caractérisé en ce que ledit ré-étirage est effectué de telle sorte que l'épaisseur de paroi (B) des parties du milieu des parties coniques (3a, 3b) devienne inférieure ou égale à 1,2 fois l'épaisseur de paroi (A) de la partie cylindrique ($B/A \leq 1,2$).

10. Procédé de fabrication d'un ballonnet de cathéter l'une quelconque des revendications 7 à 9, caractérisé en ce que ledit réétirage est effectué sur les parties coniques (3a, 3b) et sur les parties de raccordement (4a, 4b) du ballonnet cru.

11. Procédé de fabrication d'un ballonnet de cathéter l'une quelconque des revendications 7 à 10, dans lequel ladite étape de gonflage radial de la paraison tubulaire (17) est effectuée dans un moule métallique.

12. Procédé de fabrication d'un ballonnet de cathéter l'une quelconque des revendications 7 à 11, caractérisé en ce que ladite étape de gonflage du ballonnet cru ré-étiré est effectuée dans un moule métallique.

13. Procédé de fabrication d'un ballonnet de cathéter l'une quelconque des revendications 7 à 12, dans lequel ledit polymère étirable est du poly(téréphtalate d'éthylène), un mélange de poly(téréphtalate d'éthylène) et d'un polyester autre que le poly(téréphtalate d'éthylène) ou une polyoléfine, ou bien un copolymère de poly(téréphtalate d'éthylène).

14. Procédé de fabrication d'un ballonnet de cathéter selon la revendication 7 ou 13, caractérisé en ce que ledit ré-étirage est effectué de telle sorte que l'épaisseur de paroi (B) des parties du milieu desdites parties coniques (3a, 3b) est supérieure ou égale à 0,3 fois l'épaisseur de paroi (A) de ladite partie cylindrique et est inférieure ou égale à 0,9 fois l'épaisseur de paroi (A) de ladite partie cylindrique ($0,3 \leq B/A \leq 0,9$).

F I G. 1

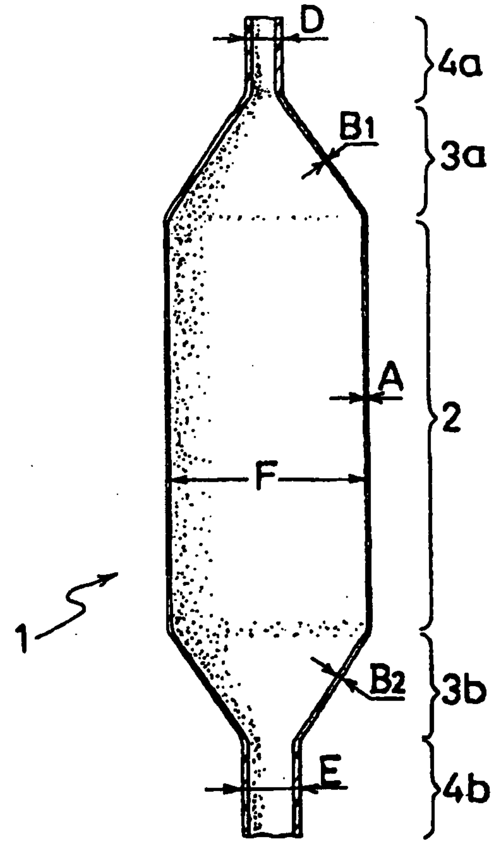

FIG. 2

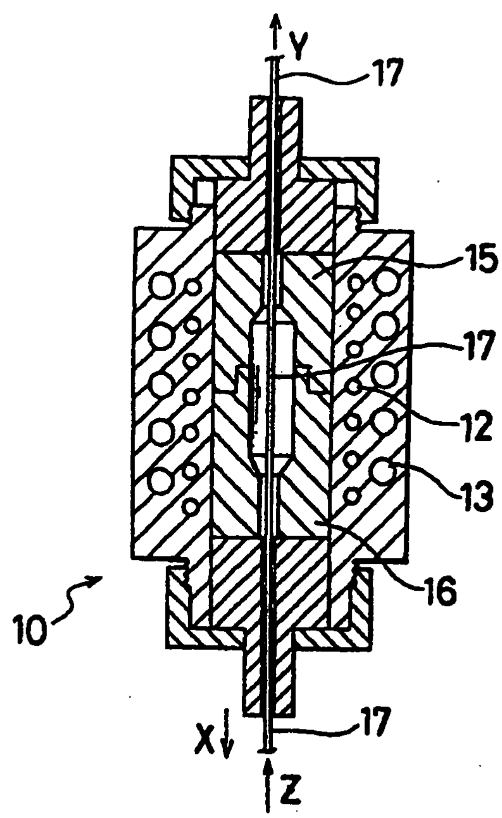

FIG. 3

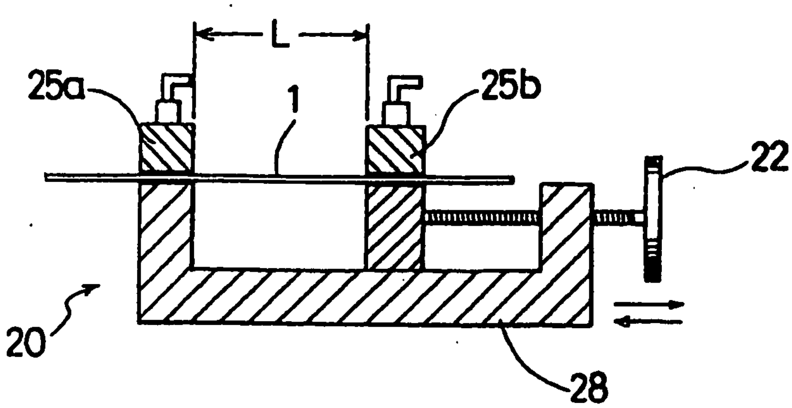

FIG. 4

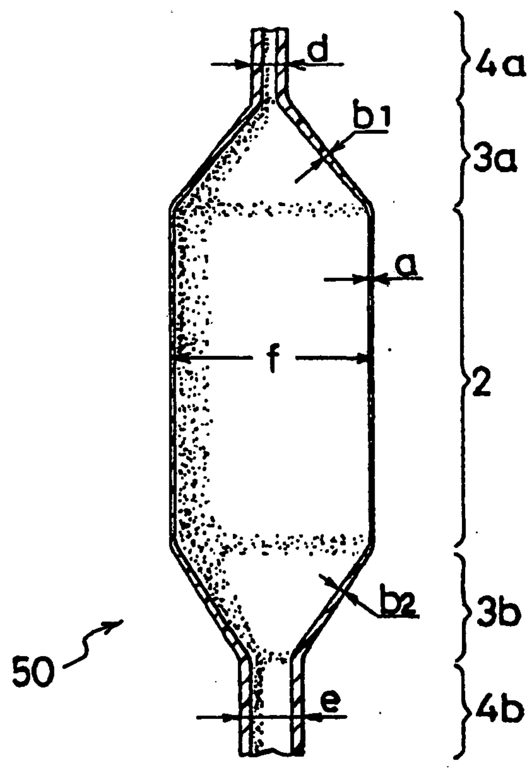

FIG. 5

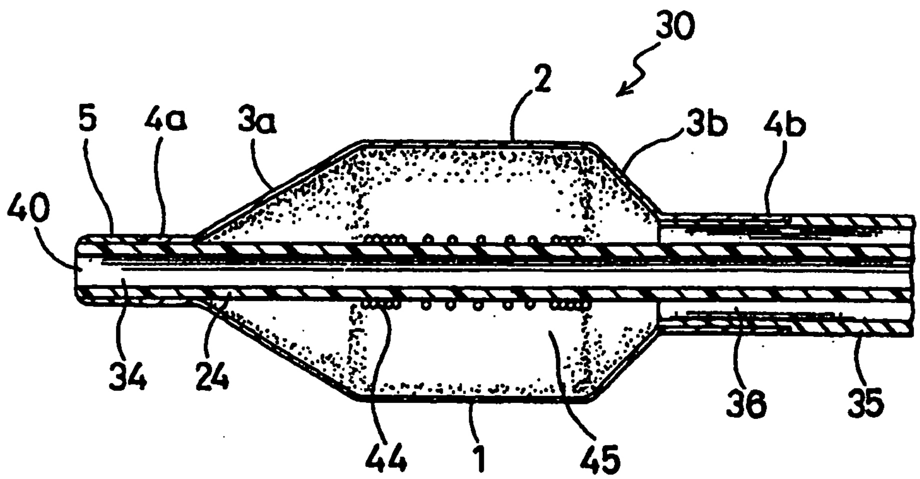
30
2
5
4a
3a
3b
4b
40
34
24
36
35
44
1
45

FIG. 6

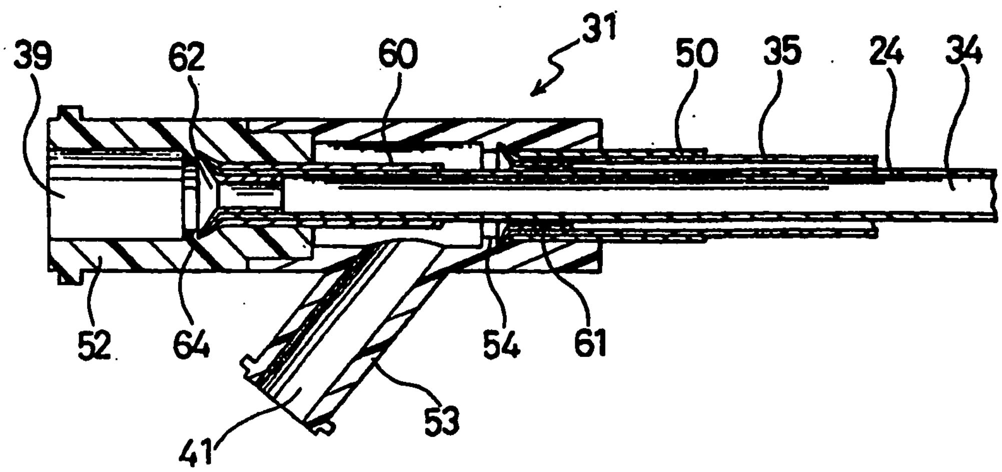
31
39
62
60
50
35
24
34
52
64
54
61
53
41

FIG.7

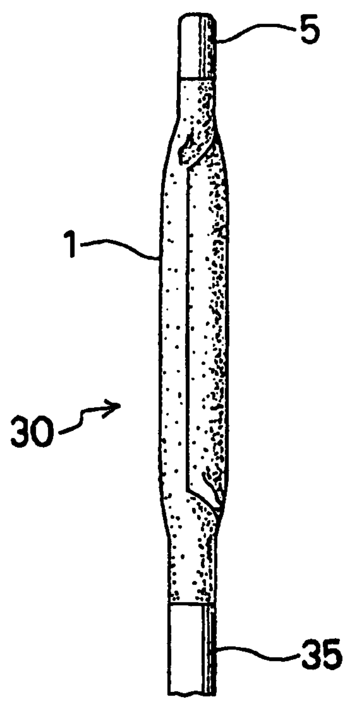

FIG.8